IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91 (GMS)
COREVALVE, INC. and MEDTRONIC COREVALVE LLC,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

EDWARDS' OPENING BRIEF IN SUPPORT OF ITS MOTION FOR AN ACCOUNTING OF DAMAGES FROM MAY 2, 2012 TO THE PRESENT

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Originally Filed: April 24, 2013
Redacted Version Filed: April 30, 2013

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I. NATURE AND STAGE OF THE PROCEEDINGS

On April 1, 2010, the jury found CoreValve, Inc. and Medtronic CoreValve LLC (collectively "Medtronic CoreValve") to be literal, willful infringers of Claim 1 of U.S. Patent 5,411,552 ("the '552 Patent"). [D.I. 313 at 2-3]. The jury rejected Medtronic CoreValve's non-infringement and non-enablement defenses and awarded approximately $74 million in damages, calculated for infringement through March 15, 2010. [*Id.* at 4-5]. Judgment was entered on the verdict on May 4, 2010. [D.I. 324]. On February 7, 2011, the Court denied Medtronic CoreValve's motion to limit the damages award to no more than $1.2 million or to grant a new trial on the issue of damages. [D.I. 429 at 20]. Medtronic CoreValve appealed. [D.I. 431]. On November 13, 2012, the Federal Circuit affirmed the jury's damages award in full. *Edwards Lifesciences AG* v. *CoreValve, Inc.*, 699 F.3d 1305, 1315-16 (Fed. Cir. 2012). On February 11, 2013, the Federal Circuit issued its mandate, having denied Medtronic CoreValve's petition for rehearing en banc and motion to stay the mandate. [D.I. 448].

The natural expiration of the '552 Patent was on May 2, 2012. While this case was on appeal, and before the natural expiration of the '552 Patent, the United States Patent and Trademark Office ("PTO") granted an interim extension of one year for the '552 Patent (through May 2, 2013). Prior to the expiration of that first interim extension, a second interim extension was granted for the '552 Patent for a second year – through May 2, 2014.

On February 22, 2013, the Court held a telephone conference with the parties to discuss the issues remaining in the case following remand. Following that conference, the parties conferred and jointly submitted a letter on March 4, 2013, setting forth a proposed schedule for an accounting and the briefing of various issues in the case. [D.I. 450].

This motion relates to damages incurred from May 2, 2012. Medtronic CoreValve has refused to participate in an accounting of those damages, on the sole ground that

the '552 Patent is in an interim extension period. As explained below, Medtronic CoreValve cannot avoid paying damages for its continued willful infringement during the '552 Patent's interim extension periods.

II. SUMMARY OF ARGUMENT

In addition to covering willful infringer Medtronic CoreValve's transcatheter heart valves, Claim 1 of the '552 Patent covers Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC's (collectively "Edwards") SAPIEN device. The SAPIEN device was subject to regulatory review by the Food and Drug Administration ("FDA") prior to Edwards being allowed to commercially market its device; this marketing was the first commercial marketing of the device. The '552 Patent had not previously been extended and Edwards' application for patent term extension was timely filed. As such, the '552 Patent qualifies for a patent term extension. On December 22, 2011, Edwards filed an application to extend the term of the '552 Patent pursuant to 35 U.S.C. § 156.

The PTO determined that "[s]ubject to final review, the subject patent is considered to be eligible for patent term extension." As required by statute, the inquiry then turned to the length of the extension. The FDA published a notice of its determination of the duration of the regulatory review period, which is the basis for calculating a patent's extension. Specifically, using the FDA's calculations, the term of the '552 Patent should be extended until March 22, 2016. This determination is subject to comment due on April 23, 2013, which the FDA will consider.[1]

[1] The threshold regulatory review period as calculated by the FDA can also be reduced if a challenger establishes that Edwards failed to pursue FDA approval with due diligence. No facts support such a challenge here. Edwards demonstrated due diligence in pursuing approval of its SAPIEN device. The time associated with its investigation and achievement of approval for such a novel implant was reasonable.

There remains no doubt that the term of the '552 Patent will be extended by the PTO. The only remaining question is the length of any such extension.

While the patent term extension process is being completed, the Director of the PTO granted two interim extensions of the '552 Patent to extend of the '552 Patent while the final extension calculations are being made. This allows Edwards to maintain its patent rights until the final patent term extension is determined.

An interim patent extension preserves all of Edwards' rights in the '552 Patent. This includes Edwards' right to damages for Medtronic CoreValve's continued willful infringement of the '552 Patent.

III. STATEMENT OF FACTS

A. The '552 Patent and the Edwards SAPIEN Device

Plaintiff Edwards AG owns the '552 Patent. [D.I. 1, ¶ 4]. Edwards AG, and its predecessor in interest to the '552 Patent, sought FDA approval to commercially market its transcatheter heart valve device ultimately named the SAPIEN device. [Exhibit A to the Declaration of Brian Egan ("Egan Decl.") at 7].

B. FDA Approval for Edwards' SAPIEN Device

FDA approval is required for Edwards to sell its SAPIEN device commercially in the United States. *See* 21 U.S.C. §§ 360c, 360e. On November 2, 2011, the FDA approved the SAPIEN device for the commercial treatment of patients with severe symptomatic native aortic valve stenosis. [Egan Decl., Ex. B].

C. Edwards' Patent Term Extension Application and Resulting Extensions

On December 22, 2011, Edwards filed a timely application for patent term extension for the '552 Patent. [Egan Decl., Ex. A at 3]. In its application, Edwards

demonstrated that (1) the '552 Patent covers the SAPIEN device; (2) the natural term of the '552 Patent had not expired before the application was submitted; (3) the natural term of the '552 Patent had never been extended; (4) Edwards AG was the owner of record of the '552 Patent; (5) the SAPIEN device had been subject to a regulatory review period prior to its commercial marketing; and (6) the permission for the SAPIEN's commercial marketing was the first permitted commercial marketing in the United States for the device. [Egan Decl., Ex. A].

On February 1, 2012, the PTO sent Edwards' patent term extension application to the FDA requesting that the FDA confirm that (1) the SAPIEN device was subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing and that (2) the application for patent term extension was filed within the sixty-day period beginning on the date the SAPIEN device was approved. [Egan Decl., Ex. C]. These are conditions necessary for approval of a patent term extension request. The PTO stated that its "review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156." [*Id.*]. The FDA responded on July 10, 2012, confirming that the SAPIEN device was subject to a regulatory review period before its commercial marketing, its commercial marketing represents the first permitted commercial marketing of the device, and the submission of the patent term extension application was timely. [*Id.*, Ex. D]. Meanwhile, on April 17, 2012, the Director of the PTO issued an order granting an interim extension while the length of the regulatory review period for the SAPIEN was determined. [Decl., Ex. E]. In the Order, the Director stated that "[t]he initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156." [*Id.*]. That Order extended the life of the '552 Patent through May 2, 2013.

On January 11, 2013, the PTO sent a second letter to the FDA stating that "[s]ubject to final review, the subject patent is considered to be eligible for patent term extension" and requesting that the FDA determine the length of the regulatory review period for the SAPIEN device under 35 U.S.C. § 156(d)(2)(A). [Egan Decl., Ex. F]. On February 19, 2013, the FDA informed the PTO Director that the regulatory review period for the SAPIEN was 2,473 days, of which 2,106 occurred during the testing phase and 367 occurred during the approval phase. [Egan Decl., Ex. G]. This determination should result in an extension of the '552 Patent to March 22, 2016. [Egan Decl., Ex. H]; *see* 37 C.F.R. § 1.777(c)-(d).

On April 1, 2013, the PTO Director issued another order granting a second interim extension for the '552 Patent, through May 2, 2014. [Egan Decl., Ex. I]. Again, the order specified that, "the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156." [*Id.*]. "Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate." [*Id.*].

D. Edwards' Motion for an Accounting of Damages From May 2, 2012

In April 2010, the jury found that Medtronic CoreValve willfully infringed the '552 Patent and awarded Edwards approximately $74 million in damages. [D.I. 313]. The verdict and award were affirmed on appeal. *See Edwards Lifesciences AG* v. *CoreValve, Inc.*, 699 F.3d 1305, 1315-16 (Fed. Cir. 2012). This award, however, covers damages for Medtronic CoreValve's infringement only up to March 16, 2010, the cut-off date for the damages period considered by the jury. [D.I. 450].

As a result, Edwards is now seeking damages for the infringement that occurred after March 16, 2010. [*Id.*]. The parties set forth a process for filings related to accountings for

damages incurred through May 1, 2012. As noted above, however, Medtronic CoreValve objected to an accounting for damages incurred after May 1, 2012, until "the Court determines the legal question of whether such recovery is available for a patent term extension period." [*Id.*].

Medtronic CoreValve is wrong as a matter of law. The '552 Patent is in full force, and Medtronic CoreValve should be held accountable for its continued willful infringement from May 2, 2012 to the present.

IV. ARGUMENT

A. An Interim Extension Provides Continuous Patent Protection for Patentees

For patents eligible for a patent term extension, an interim extension ensures that the patentee can continue to enforce its patent rights while the FDA and PTO calculate the length of the extension. *See* 35 U.S.C. § 156(e)(2); H.R. Rep. No. 98-857 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 ("Interim extension . . . is intended to provide time for the completion of any outstanding requirements.").

Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984 to eliminate distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 (1990); Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified as amended at 35 U.S.C. § 156). The statute encourages research and development in areas like medical devices and pharmaceuticals where lengthy regulatory review periods devalue a party's patent. *See Pfizer, Inc.* v. *Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004). If, as here, a patentee submits a timely extension application for a patent claiming a medical device, and that device was subject to regulatory review during which the

device could not be commercially sold in the United States, then the patentee is entitled to a patent term extension. *See Merck & Co., Inc.* v. *Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) ("[U]se of the word "shall" indicates that if the enumerated list of requirements is met, the patent term is entitled to be extended."); 35 U.S.C. § 156.

The process of determining the length of a patent term extension itself requires a period of regulatory review. First, the PTO Director determines whether an application meets the basic criteria. [Egan Decl., Ex. J]. Then, the PTO Director sends the application to the FDA, asking the FDA to confirm in writing whether the product was subject to a regulatory review period before the first permitted commercial marketing of the product. [*Id.*] The PTO also asks the FDA to inform the PTO whether the patent term extension application was submitted within sixty days after the product was approved. [*Id.*] The PTO asks these questions so that it can determine whether the patent is eligible for an extension under 35 U.S.C. § 156(g). [*Id.* at 17,831]. If a patent is not eligible for extension, the Director will dismiss the application. [Egan Decl., Ex. K] Otherwise, the Director will ask the FDA to determine the applicable regulatory review period. 35 U.S.C. § 156(d)(2)(A). From there, the FDA must follow the statutory procedures to determine the effective regulatory review period in order for the PTO to determine the length of the extension. 35 U.S.C. § 156(d)(2)(B).

Critical required steps for a patent term extension have successfully been completed in the '552 Patent's extension application process. Edwards submitted a timely extension application for the '552 Patent, which claims a medical device. The '552 Patent covers the SAPIEN device. [Egan Decl., Ex. A; Ex. D]. The PTO sent Edwards' application to the FDA, asking the FDA to confirm in writing whether the SAPIEN device was subject to a regulatory review period before its first commercial marketing and whether the application for

patent term extension was filed within the sixty-day period beginning on the date the product was approved. [Egan Decl. Ex. C]. The FDA confirmed these facts. [*Id.*, Ex. D]. The PTO then asked the FDA to determine the applicable regulatory review period for the SAPIEN device. [*Id.*, Ex. F]. The PTO determined that "[s]ubject to final review, the subject patent is considered to be eligible for patent term extension." [*Id.*]. The FDA then determined that the applicable regulatory review period is 2,473 days, of which 2,106 days occurred during the testing phase and 367 days occurred during the approval phase. [*Id.*, Ex. G; Ex. H]. Based on this, the '552 Patent should be extended until March 22, 2016. [*Id.*, Ex. H]; *see* 37 C.F.R. § 1.777(c)-(d).

FDA procedures permit challenges to the agency's calculation of the review period and Edwards' due diligence prior to a determination of the final length of time for extending the '552 Patent. *See* 21 C.F.R § 10.40; 35 U.S.C. § 156(d)(2)(B). If there is no challenge, then the FDA will notify the PTO that the regulatory review period identified in its Federal Register notice constitutes the agency's final determination. [Egan Decl., Ex. J]. After reviewing the final length of time, the Director of the PTO issues a Notice of Final Determination, which states how long the patent term is extended. 37 C.F.R. § 1.750. Only these steps remain to finalize the extension for the '552 Patent.

With such a lengthy process, many patents might otherwise expire before they are ever granted a final certificate of extension. Therefore, Congress included a provision enabling eligible patents to receive interim extensions if the patent would expire before the length of the extension is calculated.[2] 35 U.S.C. § 156(e)(2).

[2] There are two provisions in 35 U.S.C. § 156 that deal with interim extensions. Section 156(e)(2) allows an interim extension where a patent would expire after a patent term extension application has been filed. That is the case here.

B. Edwards Received Two Interim Extensions

The record in this case is indisputable. The natural date of expiration of Edwards' '552 Patent was May 2, 2012. [D.I. 1-1]. To date, the Director of the PTO has issued two orders granting interim extensions for the '552 Patent. [Egan Decl., Exs. E, I]. The PTO determined that the '552 Patent is eligible for extension under § 156(g) and submitted Edwards' application to the FDA for a determination of the regulatory review period. [*Id.*, Ex. F]. In its orders granting the interim extensions, the PTO explained that "the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156," but "[b]ecause the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate." [*Id.*, Exs. E, I].

C. Medtronic CoreValve's Infringing Products Are Covered by the Extended '552 Patent

The '552 Patent claims a product. As such, during the period of the patent term extension "the rights derived from [the] patent" will be for "any use approved for the product." 35 U.S.C. § 156(b)(1). The current approved use for the SAPIEN device is aortic valve replacement in patients with severe symptomatic native aortic valve stenosis. [Egan Decl., Exs. B, L]; *see* Section III.B., *supra*.

[redacted]

D. Edwards Is Entitled to Damages During the Interim Extension Periods

The PTO Director has twice granted one-year interim extensions of the '552 Patent, *see* Section III.C., *supra*, because he "determine[d] that the patent is eligible for extension." 35 U.S.C. § 156(e)(2).

There is no doubt that the extensions of the '552 Patent cover Medtronic CoreValve's infringing products. And there is no question that a final extension will issue. The FDA has already determined, subject to final approval, the regulatory review period, which should extend the '552 Patent until March 22, 2016. Edwards is entitled to enforce the '552 Patent during the extension period. *See Ortho-McNeil Pharm., Inc.* v. *Lupin Pharms., Inc.*, 603 F.3d 1377, 1382 (Fed. Cir. 2010) (upholding injunction during extended patent term).

Further, there is no reason to allow Medtronic CoreValve to delay paying damages during an interim extension. Edwards is entitled to damages for the willful infringement of its patent during the full term of the patent. *See* 35 U.S.C. § 284; *see also Fresenius USA, Inc*. v. *Baxter Int'l, Inc.*, 582 F.3d 1288, 1303 (Fed. Cir. 2009) ("A damages award for pre-verdict sales of the infringing product does not fully compensate the patentee because it fails to account for post-verdict sales . . . ."); *Finjan, Inc.* v. *Secure Computing Corp.*, 626 F.3d 1197, 1212-13 (Fed. Cir. 2009) ("[T]he district court should have awarded compensation for any infringement prior to the [entry of the] injunction."). The full term of a patent includes any period of interim extension. 35 U.S.C. §156(e)(2); 37 C.F.R. §1.760. This law, combined with the judgment against Medtronic CoreValve for willful infringement, entitles Edwards to damages for Medtronic CoreValve's continuing willful infringement during the interim extension periods. *See Ortho-McNeil Pharm., Inc.* v. *Mylan Labs, Inc.*, 04-1689, 2006 U.S. Dist. LEXIS 34476 (D.N.J. May 30, 2006) (allowing an infringement action to proceed where the patentee held an interim extension of the asserted patent).

Medtronic CoreValve's objection to an accounting to bring damages current is simply an attempt to postpone the inevitable and force Edwards to continue to spend money

litigating this case. The time has come for Medtronic CoreValve to pay the damages owed for its continued willful infringement.

V. CONCLUSION

For these reasons, Edwards respectfully requests that the Court order a prompt accounting for damages from Medtronic CoreValve's continuing infringement of the '552 Patent from May 2, 2012 to the present.

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April 24, 2013

CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2013 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 30, 2013 upon the following in the manner indicated:

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